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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,557	08/22/2001	Erik Gunther	GUNE117293	8854

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,557

Applicant(s)

GUNTHER, ERIK

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
4a) Of the above claim(s) 5, 12-17 and 22-31 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 6-9, 18-21, 32 and 35-37 is/are rejected.
7) ☒ Claim(s) 3, 4, 10, 11, 33, & 34 is/are objected to.
8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Applicants' arguments, filed 10/25/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-9, 18-21, 32, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (P/N 6,368,794).

This rejection is reiterated and maintained from the previous office action, mailed 10/6/04.

Applicant argues that Daniel et al. does not describe evaluating efficacy of treatments with the disclosed polynucleotides and polypeptides. In response instant claims 1 and 2, for example, lack any polynucleotides or polypeptides limitations regarding such efficacy evaluation. Thus, applicant's argument is moot as not being directed to any corresponding instant claim limitation and therefore non-persuasive. Applicant's argument is additionally non-persuasive because Daniel et al. at column 10, lines 54-67, clearly does describe, contrary to said argument, the evaluation and

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monitoring of treatment utilizing such materials. Applicant thus also argues that impermissible hindsight has been utilized to support this rejection. In response, disclosure within Daniel et al. has been again pointed to consistent with the previous office action of practices supporting the rejection clearly set forth in the reference without any need to pick and choose. Applicant then argues that Daniels et al. does not disclose or suggest treating a sample with "at least...uncharacterized specific pharmacological activity" and quote a dictionary regarding pharmacology and therapeutic. These quotes lack any indication of what is meant by "specific" in the phrase "specific pharmacological activity". The generic definitions thus fail to support the argument that the Daniel et al. descriptions are not directed to "uncharacterized specific pharmacological activity" as in the instant claims. That is, the Daniel et al. analytes are generally connected to cancerous or precancerous tissues as set forth in the previous office action and are not specific as to what pharmacological or therapeutic activity that they have. Thus, applicant has failed to distinguish the Daniel et al. analytes from those of the instantly claimed invention. Applicant then goes on to admit that the Daniel et al. practice is directed to therapeutic treatments including effective dose or therapeutic methods but only then reiterate the argument directed to uncharacterized specific pharmacological activity. This argument has been responded to above as being non-persuasive and is equally non-persuasive here. Applicant lastly argues that monitoring or evaluating the efficacy of a therapeutic treatment is different from identifying an analyte. In response, Daniel et al. was described in previous office actions as monitoring the efficacy of a treatment with an analyte. Applicant has alleged

that this does not identify an analyte but without factual support or any argument that is seen regarding previously set forth description in Daniel et al. and thus is non-persuasive as not directed to the basis for this rejection.

CLAIM OBJECTIONS

Claims 3, 4, 10, 11, 33, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 5, 12-17, and 22-31, drawn to an invention nonelected without traverse in the Paper filed 10/10/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 6, 2005

 3/6/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER